

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: December 21, 2001

MAR 27 2002

510(k) number: K014251

Applicant Information:

NTERO Surgical, Inc.
1137D San Antonio Rd
Palo Alto, CA 94303

Contact Person: D. Bommi Bommannan, PhD, JD
Phone Number: (650) 428-1000 ext. 101
Fax Number: (650) 428-0700

Device Information:

Classification: Class II
Trade Name: NTERO HOTROD™ System
Classification Name: Electrosurgical Device and accessories (21 CFR 878.4400)

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the NTERO RF Sleeve (K992572), Valleylab BiSure Laparoscopic Bipolar Forceps (K983743), and VNUS Closure System (K974521).

Intended Use:

The NTERO HOTROD™ System is intended to coagulate tissue during surgical procedures.

Test Results:

Performance

Results of animal testing demonstrate that the NTERO HOTROD™ System is safe and effective for its intended function.

Biocompatibility

The materials in direct tissue and blood contact used in the NTERO HOTROD™ System have been shown to be biocompatible.

Summary:

Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 27 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NTERO Surgical, Inc.
D. Bommi Bommannan, Ph.D., JD
President and CEO
1137D San Antonio Road
Palo Alto, California 94303

Re: K014251

Trade Name: NTERO Hotrod System™
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories;
Regulatory Class: II
Product Code: GEI
Dated: December 21, 2001
Received: December 26, 2001

Dear Dr. Bommannan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for 
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K014 251

Device Name: NTERO HOTROD System

Indications for Use:

The NTERO HOTROD System is intended to coagulate tissue during surgical procedures.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014257

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use _____
(Optional Format 1-2-96)